EXHIBIT B

BEFORE THE UNITED STATES JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

In re: Zimmer NexGen Knee Products Liability Litigation	MDL Docket No. 2272

AFFIDAVIT OF MICHELLE ZAWADZKI

Michelle Zawadzki, being duly sworn, states as follows:

1. I am over 18 years of age and have personal knowledge of the facts and representations set forth in this affidavit.

2. I am a Quality and Compliance Staff Engineer at Zimmer, Inc. ("Zimmer"), and I have worked at Zimmer since 1988. I hold a Bachelor's Degree in Engineering from Purdue University and a Master's Degree in Engineering from the University of Akron.

3. From 1988 to 2008, my work at Zimmer involved different aspects of the design and marketing of Zimmer knee replacement products. In the course of discharging my various duties and responsibilities at Zimmer, I have acquired certain personal knowledge about the CR Flex-Fixed Femoral Components, the LPS Flex-Fixed Femoral Components, the *Gender Solutions* CR Flex-Fixed Femoral Components, the *Gender Solutions* LPS Flex-Fixed Femoral Components, and the MIS Total Knee Procedure Stemmed Tibial Component Fixed Bearing Surface Tibia ("MIS Tibial Component") (collectively, "the "Products"). Likewise, some of my knowledge about the Products is based on information available to me as an employee of Zimmer from Zimmer documents or other Zimmer resources.

A. Background

4. Zimmer introduced the LPS Flex-Fixed Precoat and Option Femoral Components in 2000. Zimmer introduced a porous version of the LPS Flex-Fixed Femoral Component in late 2009 and early 2010.

5. Zimmer introduced three different CR Flex-Fixed Femoral Component products for sale in 2003: the CR Flex-Fixed Precoat Femoral Component; the CR Flex-Fixed Option Femoral Component; and, the CR Flex-Fixed Porous Femoral Component.

6. Zimmer introduced the MIS Total Knee Procedure Stemmed Tibial Component Fixed Bearing Surface Tibia in 2005.

7. Zimmer began selling the Gender Solutions LPS Flex-Fixed Option Femoral Component and Gender Solutions CR Flex-Fixed Precoat Femoral Component in 2006. In 2008, Zimmer supplemented these Gender Solutions products by offering a porous (uncemented) Gender Solutions LPS Flex-Fixed Femoral Component and Gender Solutions CR Flex-Fixed Femoral Component.

B. Distinctions Among Product Designs

8. There are key distinctions between the designs of the above-referenced femoral components and the MIS Tibial Component – namely, that they are used to treat entirely different bones within the knee. There also are key design distinctions among the femoral products.

9. As an initial matter, some of the Products are precoated for use with cement and others have a porous coating for bone ingrowth. Precoated products have a poly methylmethacrylate coating ("PMMA") to which surgeons bond cement intraoperatively. In

contrast, porous femoral components are specifically designed to allow a patient's bone tissue to grow into the porous surface of the implant, which is made of Co-Cr-Mo fiber mesh.

10. In addition, the LPS Flex-Fixed and CR Flex-Fixed components differ between one another. "LPS" products are designed to be used during knee replacement surgery in the *absence* of a posterior cruciate ligament, and their design includes unique features that provide stability to the patient's knee that are not included in other femoral components.[1] "CR" products, in turn, are designed to be used during knee replacement surgery that *preserves* the patient's posterior cruciate ligament.[2] The LPS Flex-Fixed and CR Flex-Fixed components also differ in that they have different radii of curvature between the femoral articular surface and the tibial articular surface. This difference is important, because it accommodates the different kinematics and motion experienced by patients who lack a posterior cruciate ligament versus those who possess a posterior cruciate ligament.

11. The Gender Solutions femoral components also differ from the other Products. First, Gender Solutions components address the bone geometry differences between genders by reducing the anterior flange thickness of the implant, contrary to other implants. Second, the design of the patellar sulcus -- the groove in which the patella tracks -- of Gender Solutions components is deeper. Third, the trochlear groove angle is different than other femoral components to accommodate the larger Q-angle of typical female anatomy. Fourth, female femurs typically are more trapezoidal-shaped and narrower in the medial-lateral (side-to-side)

---

[1] "LPS" stands for *Legacy* Posterior Stabilized. The design of the LPS Flex-Fixed Femoral Components includes a metal posterior cam, which corresponds to a spine mechanism on the polyethylene tibial articular surface. The interaction of the cam/spine mechanism increase subluxation resistance. The cam/spine mechanism is not present in the CR Flex-Fixed Femoral Components and their articular surfaces.

[2] "CR" stands for cruciate retaining.

dimension when compared to a male femur. *Gender Solutions* products, thus, are designed differently to mimic that dimension.

C. Potential Witnesses And Documents

12. Six different design teams of Zimmer employees designed the following components: (1) CR Flex-Fixed Femoral Components, (2) LPS Flex-Fixed Precoat and Option Femoral Components, (3) LPS Flex-Fixed Porous Femoral Component, (4) Gender Solutions Precoat CR Flex-Fixed and Gender Solutions Option LPS Flex-Fixed Femoral Components, (5) Gender Solutions Porous CR Flex-Fixed and Gender Solutions Porous LPS Flex-Fixed Femoral Components, and (6) MIS Total Knee Procedure Stemmed Tibial Component Fixed Bearing Surface Tibia. While there may have been some limited overlap between the employees on teams, that overlap was minimal, and the design teams were wholly separate. The teams attended separate meetings and developed unique blueprints for the final designs of the Products within their teams.

13. The Zimmer employees charged with developing the manufacturing process for the femoral components within the Products were different from those charged with developing the manufacturing process for the MIS Tibial Component.

14. Moreover, these products were submitted to the United States Food & Drug Administration for clearance under different 510(k) regulatory submissions, and the Zimmer employees involved in preparing the submissions and communicating with the FDA were different.

15. The Zimmer marketing employees charged with developing the strategic marketing plans for the above-referenced products also were different and addressed the Products at different times with unique plans. Again, while some limited overlap may exist as Zimmer employees changed positions over the years during which the products were released, the marketing personnel responsible were different.

16. After the release of each of the above-described products, different teams of Zimmer employees became responsible for the post-market surveillance of the products. While some overlap may exist, different teams of Zimmer employees were responsible for post-market surveillance of the products at different times.

17. Just as the Zimmer employees with knowledge of the Products differ, so too do the documents involved in the design, manufacturing, inspection, regulatory approval, marketing, and post-marketing surveillance of the Products. Specifically, Zimmer's blueprints, specifications, design rationale documents, design history documents, models, packaging specifications, labels, and numerous other design documents for the Products are different.

18. The manufacturing documents for the Products also differ. The components are manufactured to different manufacturing specifications, using different manufacturing programs and routers, and different inspection sheets and gauges with different dimensions and parameters. In addition, each manufacturing lot of each component will have its own, unique manufacturing history records, which show all steps in the manufacture of the lot.

19. The labeling documents at issue for the Products also differ, and communications with surgeons regarding the Products also differ. Specifically, the Surgical Techniques used to instruct surgeons on implantation of the products differ, and there are

differences among the Package Inserts that accompany the products and contain the warnings, indications, and contraindications for the products.

20. The regulatory applications for the Products differ. The FDA cleared the Products at different times from 1999 to 2006 after receiving eight different 510k regulatory filings. The regulatory approval documents for the MIS Tibial Component, for example, differ from the regulatory approval documents for any other component. Likewise, the 510(k) application for the Gender Solutions products is wholly separate from the 510(k) applications for the remaining Products.

21. Strategic marketing documents for the components at issue also differ. The strategic marketing of each of these components occurred at different times and necessarily resulted in different marketing plans, meeting minutes, and other strategic marketing documents.

22. Likewise, post-marketing surveillance of the products inevitably resulted in the creation of different documents. Post-marketing surveillance began at the time of product launch, thus, documents related to post-marketing surveillance of the products necessarily cover different time periods and were created by different employees.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on June 28, 2011

Michelle Zawadzki